OMB

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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**Food and Drug Administration**

**[Docket No. 02N–0516]**

## Agency Information Collection Activities; Submission for OMB Review; Comment Request; Request for Samples and Protocols

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax or electronically mail written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be electronically mailed to sshapiro@omb.eop.gov or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX: 202–395–6974.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA 250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Request for Samples and Protocols—(OMB Control Number 0910–0206)—Extension**

Under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262), FDA has the responsibility to issue regulations that prescribe standards designed to ensure the safety, purity, and potency of biological products and to ensure that licenses for such products are only issued when a product meets the prescribed standards. Under § 610.2 (21 CFR 610.2), FDA may at any time require manufacturers of licensed biological products to submit to FDA samples of any lot along with the protocols showing the results of applicable tests before marketing the lot of the product. In addition to § 610.2, there are other regulations in part 660 (21 CFR part 660) that require the submission of samples and protocols for specific licensed biological products: §§ 660.6 (Antibody to Hepatitis B Surface Antigen), 660.36 (Reagent Red Blood Cells), and 660.46 (Hepatitis B Surface Antigen). Section 660.6(a) provides requirements for the frequency of submission of samples from each lot of Antibody to Hepatitis B Surface Antigen product, and § 660.6(b) provides the requirements for the submission of a protocol containing specific information along with each required sample. For § 660.6 products subject to official release by FDA, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history or manufacture of the product, including all results of each test for which test results are requested by the Center for Biologics Evaluation and Research (CBER). After official release is no longer required, one sample along with a protocol is required to be submitted at an interval of 90 days. In addition,

samples, which must be accompanied by a protocol, may at any time be required to be submitted to FDA if continued evaluation is deemed necessary. Section 660.36(a) requires, after each routine establishment inspection by FDA, the submission of samples from a lot of final Reagent Red Blood Cell product along with a protocol containing specific information. Section 660.36(a)(2) requires a protocol contain information including, but not limited to, manufacturing records, test records, and test results. Section 660.36(b) requires a copy of the antigenic constitution matrix specifying the antigens present or absent to be submitted to FDA at the time of initial distribution of each lot. Section 660.46(a) provides requirements for the frequency of submission of samples from each lot of Hepatitis B Surface Antigen product, and § 660.46(b) provides the requirements for the submission of a protocol containing specific information along with each required sample. For § 660.46 products subject to official release by FDA, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history or manufacture of the product, including all results of each test for which test results are requested by CBER. After notification of official release is received, one sample along with a protocol is required to be submitted at an interval of 90 days. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to FDA if continued evaluation is deemed necessary. Samples and protocols are required by FDA to help ensure the safety, purity, or potency of the product because of the potential lot-to-lot variability of a product produced from living organisms. In cases of certain biological products (e.g., Albumin, Plasma Protein Fraction, and specified biotechnology and specified synthetic biological products) that are known to have lot-to-lot consistency, official lot release is not normally

required. However, submissions of samples and protocols of these products may still be required for surveillance, licensing, and export purposes, or in the event that FDA obtains information that the manufacturing process may not result in consistent quality of the product. The following burden estimate is for protocols required to be submitted with each sample. The collection of samples is not a collection of information under 5 CFR 1320.3(h)(2). Respondents to the collection of information under § 610.2 are manufacturers of any licensed biological product. Respondents to the collection of information under §§ 660.6(b), 660.36(a)(2) and (b), and 660.46(b) are manufacturers of the specific products referenced previously. The estimated number of respondents for each regulation is based on the annual number of manufacturers that submitted samples and protocols for biological products including submissions for lot release, surveillance, licensing, or export. There are an estimated 329 manufacturers of licensed biological products, however, based on information obtained from FDA's database system, approximately 83 manufacturers submitted samples and protocols in fiscal years 1999 and 2000, under the regulations cited previously. FDA estimates that approximately 76 manufacturers submitted protocols under § 610.2 and 7 manufacturers submitted protocols under the regulations for the specific products. The total annual responses are based on the annual average of FDA's final actions completed in fiscal years 1999 and 2000, which totaled 6,747, for the various submission requirements of samples and protocols for biological products. The rate of final actions is not expected to change significantly in the next few years. The hours per response are based on information provided by industry. The burden estimates provided by industry ranged from 1 to 5.5 hours. Under § 610.2, the hours per response are based on the average of these estimates

The burden estimates provided by industry ranged from 1 to 5.5 hours. Under § 610.2, the hours per response are based on the average of these estimates and rounded to 3 hours. Under the remaining regulations, the hours per response are based on the higher end of the estimate (rounded to 5 or 6 hours) because more information is generally required to be submitted in the protocol than under § 610.2.

In the **Federal Register** of December 27, 2002 (67 FR 79127), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received one comment on the information collection in response to the 60-day notice.

The comment recommended that we should review the regulations under § 610.2(a) concerning lot release and consider modifications to reflect current manufacturing technology standards in light of industry's ability to control and test products to ensure identity, purity, and potency. The comment provided some suggestions to consider regarding the lot release requirements.

The comment's suggested regulatory revisions that pertain to provisions or matters that are outside the scope of the proposed information collection. Consequently, we decline to adopt the comment's recommendations.

FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 610.2 | 76 | 86.5 | 6,574 | 3 | 19,722 |
| 660.6(b) | 4 | 28.5 | 114 | 5 | 570 |
| 660.36(a)(2) and (b) | 1 | 1 | 1 | 6 | 6 |
| 660.46(b) | 2 | 29 | 58 | 5 | 290 |
| Total | 83 | | 6,747 | | 20,588 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: 5-15-03

May 15, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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